

NIAID 214.1 (10103730)

REMARKS

Entry of the amendment is requested. Claims 17-29 will replace claims 1-16. Claims 17-29 are presented in a format which utilizes "consisting essentially of" as a transitional phrase. See MPEP 2111.03 for the USPTO position on such language.

When such language is used, applicants are charged with showing what the basic and novel characteristics of the invention are.

The specification clearly explains the invention. Specifically, the methods of the invention utilize formulations as compositions which could be referred to as "pro-drugs." These are components which, due to their structure, are converted to active compounds, or "drugs," by the body, when they are administered to the body. In the present invention, again as is made clear throughout the specification, the invention requires application to tissue, followed by permeation through the tissue, e.g., skin. In order for permeation to occur, the prodrugs, or "first compound" of the claims must possess certain partition qualities, which can be expressed via a "log Po/w" value.

The ability to permeate, however, is not enough. The invention also requires that the "first compound" of the claims be converted to a vasodilator, such as niacin. Niacin is well known as a powerful vasodilator; however, what is not known is that derivatives of niacin, e.g., can be applied to tissue, where they permeate the tissue and are converted to niacin, thus leading to oxygenation of the tissue. As noted, supra, in the case of all of these compounds, niacin esters in particular, a log Po/w value below 6 must be a property of the administered compound.

The "first compound" is the active ingredient of the invention, hence the "consisting essentially of" language. The goal of the invention is simple: to oxygenate the skin. Hence, while the formulations may, e.g., contain inert ingredients, the formulations oxygenate the skin, and should they have additional beneficial qualities, these are due to the "first compound," not due to other materials present therein.

Turning to the office action, the examiner has rejected all of claims 1-7 and 9-16, under 35 U.S.C. §112, first paragraph, as allegedly being non-enabled. The examiner concedes enablement

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for C₁-C₁₈ esters of niacin. Nonetheless, the examiner rejects all of claims 5, 6, 7, 9 and 10 which are directed to said compounds.

The examiner appears to be troubled by the use of "derivative" as in "derivative of a vasodilator compound."

The replacement claims do not employ this term, but applicants would be remiss if they did not point out that they present a clear and complete definition of "derivative" at page 9, lines 8-11. The examiner is directed thereto.

With respect to the rejections under 35 U.S.C. §112, second paragraph, "log Po/w" replaces log P" in the claims, "about" is absent, and claim 29 refers to claim 28, establishing antecedent basis for "ester."

The examiner has rejected claims 1, 3-5, 11-16 under 35 U.S.C. §103 in view of Rine plus Le plus Otsuka. This rejection is traversed.

Nourishment is a key feature of the invention defined by Rine. See column 1, lines 10-11:

"Further, the composition of the present invention provides complex nutrients which nourish the shaft of hair."

A review of the Rine formulations shows vitamins B₁₂, B₆, C and E as being contained therein.

Such formulations do not consist essentially of the compounds described in the claims. One can certainly argue that Otsuka might be combined with Rine, although one finds no reason to conclude this in the references; however, even if one did combine the two references, the formulation would not consist essentially of the vasodilator.

To the same end, it is urged that the rejection over Abe plus Otsuka must fail. According to Abe:

"The composition improves percutaneous absorption of an active ingredient."

In other words, Abe does not see the nicotine acid esters as active ingredient per se. A laundry list of active ingredients are set forth at column 5, lines 16-61. None of these active ingredients have been shown to satisfy the structures of the claim. Indeed, one finds no mention within Abe of the

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aim or purpose, of the invention claimed in the present application, which is improved oxygenation of tissuc. Hence, it cannot be said that Abe, taken with Otsuka, makes out a prima facie case.

Further, case law establishes that when a reference teaches the opposite effect of what is claimed, it per se cannot be deemed to render a claimed invention obvious. The Otsuka reference teaches using any of a number of compounds, such as butyl benzoate, to improve the permeation of an active compound. In contrast, applicants point out that butyl benzoate is an example of a compound, i.e., an ester of a compound that does not have a vasodilatory effect, and thereby retards the activity of the active ingredient. Please see, e.g., page 8, lines 16-20 of the specification.

In view of the foregoing, withdrawal of the rejections and allowance of claims 17-29 are believed proper and are urge.

Respectfully submitted,

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